POSTER

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Low Clinical Event Rates In Real-World Patients Receiving the XIENCE V® Everolimus-Eluting Stent (EES) Via Direct Stenting: One-Year Results From the XIENCE V USA Study

David R Rutledge[1], James B Hermiller[2], Vivian Mao[1], Weiying Zhao[1], Alena V Pechonkina[1], Jin Wang[1], Lalitha Jonnavithula[1], Charles A Simonton[1], Mitchell W Krucoff[3], Krishnankutty Sudhir[1]
[1]Abbott Vascular, Santa Clara, CA;[2]Heart Center of Indianapolis, Indianapolis, IN;[3]Duke University Medical Center, Durham, NC

Background: The XIENCE V® EES (XIENCE V; Abbott Vascular) showed superior angiographic and clinical outcomes to TAXUS PES in the SPIRIT II, III, and IV randomized controlled trials. As predilation was mandatory in these earlier trials, very limited data existed on the clinical outcomes of XIENCE V with direct stenting. By contrast, the XIENCE V USA study allowed direct stenting during the index procedure, thus permitting evaluation of XIENCE V in this subgroup of patients.
Methods: XIENCE V USA is a multicenter, real-world post-approval study of XIENCE V. Between July and December 2008, 5054 consecutive patients undergoing PCI with XIENCE V were enrolled. Clinical endpoint events were adjudicated by an independent Clinical Events Committee. In this analysis, 1-year clinical outcomes in single-lesion patients in whom direct stenting was performed during the index procedure (n=1291) were compared to patients in whom predilation was performed (n=2067).
Results: Lesions treated with direct stenting were shorter and less complex. Post dilatation was performed in 44.7% vs 58.9% (direct vs. non-direct), p < 0.0001. Procedural success was 98.8% vs. 98.5% (direct vs. non-direct), p=0.449. At 1 year, 79.0% of patients in the direct stenting subgroup remained on dual antiplatelet therapy vs. 80.5% in the non-direct stenting subgroup (p=0.299). Overall and late (30 days-1 year) ARC-defined definite/probable stent thrombosis (ST) rates were 0.7% vs. 0.4% (direct vs. non-direct), p=0.222, and 0.3% vs. 0.2%, p=0.492, respectively. Rates of TLR and target lesion failure (TLF: composite of cardiac death, ARC-defined MI attributed to target vessel, and CI-TLR) were 3.2% vs. 3.5% (direct vs. non-direct), p=0.691, and 6.2% vs 6.9%, p=0.471, respectively.
Conclusions: In this large, multicenter, real-world study, patients in the direct stenting subgroup treated with XIENCE V had low rates of ST, TLR, and TLF at 1year that were similar to patients who underwent predilation. These results demonstrate the safety and efficacy of direct stenting with XIENCE V in less complex lesions.

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Stent Expansion After Additional Non-compliant Balloon High-pressure Inflation In Patients With Drug-eluting Stent Underexpansion: An Intravascular Ultrasound Study

Sang-Wook Kim[1], Gary S Mintz[2], Akiko Maehara[2], Wang Soo Lee[1], Young Joon Hong[3], Sung Yun Lee[4], Yun Joo Min[1], Kwang Je Lee[4], Tae Ho Kim[1], Chee Jeong Kim[1], Wang Seong Ryu[1], Neil J. Weissman[5]
[1]Chung-Ang University Hospital, Seoul, Korea, Republic of[2]Cardiovascular Research Foundation, New York, NY;[3]Chonnam National University Hospital, Gwangju, Korea, Republic of[4]Inje University, Ilsan Paik Hospital, Ilsan, Korea, Republic of[5]Washington Hospital Center, Washington, DC

Background: Stent underexpansion is one of the causes of drug-eluting stent (DES) failure (restenosis and thrombosis).
Methods: We used intravascular ultrasound (IVUS) to evaluate stent expansion in patients with DES underexpansion (minimal stent area [MSA] <5mm^2) in 52 lesions (50 pts) that had IVUS analysis before and after DES implantation. Additional non-compliant (NC) balloon high-pressure inflation (>18atm) was used, and post-NC balloon IVUS was repeated in all pts. Negative remodeling was defined as a remodeling index (lesion/reference arterial area) <0.95. % stent expansion was defined as minimal stent area(MSA)/average reference lumen area.
Results: Pt age was 62±10.4 yrs, and 19% were diabetic. Pre-DES the distal reference lumen area was 4.78±1.34mm^2, minimal lumen area was 2.53±0.53mm^2, and remodeling index was 0.98±0.08. MSA was increased after additional NC balloon inflation (p=0.004), and % stent expansion was improved (p=0.002); however, stent underexpansion still persisted as 56% (29/52) had a MSA <90% of distal reference lumen and in 62% (32/52) the MSA was still <5mm^2.

	pre	Post-stent	Post-NC	p-value
Proximal reference				
Vessel volume (mm^3)	67.625± 23.890	63.311± 25.180	61.551± 26.675	0.727
Lumen volume (mm^3)	38.166± 13.451	34.088± 14.019	32.657± 13.490	0.404
Plaque volume (mm^3)	29.459± 14.509	29.222± 14.365	28.892± 16.041	0.992
Target Lesion				
Vessel volume (mm^3)	263.14±119.71	307.87±138.61	316.65±146.80	0.032
Stent volume (mm^3)		134.25±54.41	146.11±60.59	0.00017
Plaque volume (mm^3)		173.61±91.27	170.53±93.35	0.386
EEM area (mm^2)		12.45± 3.25	12.64± 3.27	0.055
Minimal stent area (mm^2)		3.94±0.69	4.67±0.89	0.004
Stent expansion (%)		74.50±15.08	87.35±15.51	0.002
Plaque area (mm^2)		7.00± 2.81	6.780± 2.647	0.102
Distal reference				
Vessel volume (mm^3)	44.50±15.07	42.03±15.57	44.46±13.56	0.825
Lumen volume (mm^3)	28.03±6.69	25.94±7.74	28.30±7.52	0.524
Plaque volume (mm^3)	16.47±11.49	16.09±10.63	16.16±10.16	0.993

Conclusion: IVUS showed that DES underexpansion can be an unsolved problem even after additional high pressure NC balloon inflation.

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Predictors and Midterm Outcomes of Cardiac Enzyme Elevation following Percutaneous Coronary Intervention with Drug-eluting Stents in Non Acute Myocardial Infarction Patients

Kanhaiya Lal Poddar[1], Seung Woon Rha[1], Sureshkumar Ramasamy[1], Ji Young Park[1,2], Kang Yin Chen[3,1], Yong Jian Li[4,1], Byoung Geol Choi[1], Yun Kyung Kim[1], Cheol Ung Choi[1], Hong Euy Lim[1], Jin Won Kim[1], Eung Ju Kim[1], Chang Gyu Park[1], Hong Seog Seo[1], Dong Joo Oh[1]
[1]Korea University Guro Hospital, Seoul, Korea, Republic of[2]Eulji General Hospital, Seoul, Korea, Republic of[3]The second Hospital of Tianjin Medical University, Tianjin, China[4]Nankai Hospital, Tianjin Medical University, Tianjin, China

Background: Predictors of post-percutaneous coronary intervention (PCI) cardiac enzyme (CK-MB or Troponin-I) elevation and its impact on the midterm clinical outcomes are yet to be ascertained in the drug-eluting stents (DES) era.
Method: A total 1,067 consecutive patients (pts) who underwent PCI with DESs from January 2004 to August 2009 were enrolled. Pts presenting with cardiogenic shock, acute myocardial infarction (AMI), received bare metal stent (BMS) and those with left main disease were excluded from the study. A total 109 (10.2 %) pts were found to have either elevation (3 times or more of upper normal limit) of CK-MB (>15 U/L) or Trop-I (>2 ng/ml) and were divided into elevated cardiac enzyme group and normal cardiac enzyme group. Important clinical and procedural predictors of post PCI cardiac enzyme elevation and its impact on midterm clinical outcomes were analyzed.
Results: Presence of old age, more use of Cilostazol, hypertension, multivessel disease, bifurcation lesion, calcified lesion, higher baseline CK-MB & Troponin-I, longer lesion length and procedural time and larger stent length were found to be associated with higher post-PCI cardiac enzyme level (Table). On multivariate analysis, pts in elevated cardiac enzyme group were found to have higher likelihood of suffering from mortality, target vessel revascularization-major adverse cardiac event (TVR-MACE) and total MACE in midterm period (Table).

Table. Significant predictors of elevated post-PCI cardiac enzymes

Variable, n (%)	Normal Cardiac Enzyme group (n=958 pts)	Elevated Cardiac Enzyme Group, (n=109 pts)	P-Value
Age	65.62±10.22	70.05±10.24	<0.001
Hypertension	634 (66.2)	86 (78.9)	0.007
Creatinine (mg/dL)	1.01±0.87	1.37±1.63	0.024
Baseline CK-MB	2.83±1.68	8.26±8.95	<0.001
Baseline Trop-I (ng/mL)	0.06±0.43	0.63±1.42	<0.001
Multivessel disease	205 (21.4)	43 (39.4)	<0.001
Bifurcation Lesion	351 (36.6)	55 (50.5)	0.007
Calcified Lesion	146 (15.2)	27 (24.8)	0.014
Lesion Length (mm)	23.83±11.00	27.49±13.74	0.012
Stent Length (mm)	24.13±6.20	25.98±6.19	0.004
Stent Diameter (mm)	2.99±0.41	2.92±0.39	0.080
Procedural Time (min)	41.86±33.45	69.33±43.42	<0.001

Midterm clinical Outcomes

Outcomes, n(%)	Normal Cardiac Enzyme group (n=958 pts)	Elevated Cardiac Enzyme Group (n=109 pts)	P-Value (Univariate Analysis)	P-Value (Multivariat Analysis	OR (95% CI)
Mortality	10 (1.0)	5 (4.6)	0.013	0.043	0.075 (0.006-0.924)
Cardiac Death	6 (0.6)	2 (1.8)	0.193	0.236	0.624 (0.128-1.482)
Q-MI	3 (0.3)	0 (0.0)	1.000	0.997	--
Repeat PCI	74 (7.7)	11 (10.1)	0.354	0.232	0.559 (0.215-1.454)
TLR	45 (4.7)	7 (6.4)	0.477	0.348	0.502 (0.162-1.558)
TVR	53 (5.5)	9 (8.3)	0.276	0.401	0.554 (0.193-1.595)

Conclusion: presence of old age, hypertension, complex lesions, adverse CK-MB and Troponin-I level on admission and longer stent predicts post-PCI cardiac enzyme elevation which translated into higher midterm mortality, TVR-MACE and total MACE.

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Comparison Of Drug-eluting Stents In Real-life Clinical Practice In Sweden: Insights From The Scaar Register

Goran K H Olivecrona[1], Elvin Kedhi[2], Elmir Omerovic[3], Stefan James[4], J. Gustav Smith[1], Bo Lagerqvist[4]
[1]Lund University Hospital, Lund, Sweden[2]Maasstad Ziekenhuis, Rotterdam, Netherlands[3]Sahlgrenska University Hospital, Gothenburg, Sweden[4]Uppsala University Hospital, Uppsala, Sweden

Background: The SPIRIT IV and COMPARE trials showed improved safety and efficacy with everolimus-eluting stents (EES) when compared to paclitaxel-eluting stents (PES) and rejected the concept of a class effect for drug-eluting stents. We compared the safety and efficacy of EES and PES in real-life clinical practice in all Swedish PCI centres, using the Swedish Coronary Angiography and Angioplasty register and also extended our analyses to include sirolimus-eluting (SES) and 1st generation zotarolimus-eluting (ZES) stents.
Methods: We studied all patients treated with at least one of these stents between Nov 2006 and Feb 2010. EES was compared individually with PES, SES and ZES for the up to 1-year incidence of clinically driven and detected in-stent restenosis, definite stent thrombosis, and all cause mortality. The Kaplan-Meier estimator was used to compute cumulative hazards and Cox proportional hazards regression to estimate hazard ratios. Propensity score methods were used to adjust for clinical and angiographic baseline differences.
Results: We included 1760, 5112, 3047 and 1778 patients treated with EES, PES, SES and ZES, respectively. The cumulative 1-year event rates and hazard of in-stent restenosis, definite stent thrombosis and all-cause mortality is presented in the table.

Stent type	n (stents)	Restenosis, % (n)	Adj. HR (95% CI)	Stent Thrombosis, % (n)	Adj. HR (95% CI)	Mortality (patients with one stent)	Adj. HR (95% CI)
EES	2823	1.8%(52)	1	0.3%(9)	1	1.9%(17/876)	1
PES	8818	3.1%(280)	2.11 (1.43-3.11)	0.8%(67)	2.3 (0.98-5.61)	3.6%(92/2498)	1.33 (0.70-2.54)
SES	4720	3.4%(161)	1.60 (1.01-2.54)	0.8%(39)	2.40 (0.85-6.73)	2.3%(41/1800)	0.81 (0.34-1.93)
ZES	2808	6.3%(178)	2.77 (1.69-4.53)	1.0%(29)	1.66 (0.48-5.82)	4.1%(46/910)	1.80 (0.70-5.15)

Conclusion: Our results corroborate findings from the SPIRIT IV and COMPARE trials in real-life clinical practice, showing that use of EES results in significantly lower rates of restenosis. Additionally, trends for reduction in definite stent thrombosis were observed when compared to PES and SES.